

to indicate the importer's liability and make a recommendation accordingly.

(c) The District Director of Customs, within 3 days of the receipt of this recommendation, whether favorable or otherwise, shall notify the importer that, the legal period of 3 months for exportation or relabeling having expired, action will be taken within 30 days to enforce the terms of the bond.

## PART 1240—CONTROL OF COMMUNICABLE DISEASES

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AUTHORITY: 42 U.S.C. 216, 243, 264, 271.

CROSS REFERENCES: For Department of Health and Human Services regulations relating to foreign quarantine, sanitation measures, and control of communicable diseases, see Centers for Disease Control's requirements as set forth in 42 CFR parts 71 and 72.

SOURCE: 40 FR 5620, Feb. 6, 1975, unless otherwise noted.

## Subpart A—General Provisions

### § 1240.3 General definitions.

As used in this part, terms shall have the following meaning:

(a) *Bactericidal treatment*. The application of a method or substance for the destruction of pathogens and other organisms as set forth in § 1240.10.

(b) *Communicable diseases*. Illnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment.

(c) *Communicable period*. The period or periods during which the etiologic agent may be transferred directly or indirectly from the body of the infected person or animal to the body of another.

(d) *Contamination*. The presence of a certain amount of undesirable substance or material, which may contain pathogenic microorganisms.

(e) *Conveyance*. Conveyance means any land or air carrier, or any vessel as defined in paragraph (n) of this section.

(f) *Garbage*. (1) The solid animal and vegetable waste, together with the natural moisture content, resulting from the handling, preparation, or consumption of foods in houses, restaurants, hotels, kitchens, and similar establishments, or (2) any other food waste containing pork.

(g) *Incubation period*. The period between the implanting of disease organisms in a susceptible person and the appearance of clinical manifestation of the disease.

(h) *Interstate traffic*. (1) The movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation which is entirely within a State or possession,

(i) From a point of origin in any State or possession to a point of destination in any other State or possession, or

(ii) Between a point of origin and a point of destination in the same State or possession but through any other State, possession, or contiguous foreign country.

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(2) Interstate traffic does not include the following:

(i) The movement of any conveyance which is solely for the purpose of unloading persons or property transported from a foreign country, or loading persons or property for transportation to a foreign country.

(ii) The movement of any conveyance which is solely for the purpose of effecting its repair, reconstruction, rehabilitation, or storage.

(i) *Milk*. Milk is the product defined in § 131.110 of this chapter.

(j) *Milk products*. Food products made exclusively or principally from the lacteal secretion obtained from one or more healthy milk-producing animals, e.g., cows, goats, sheep, and water buffalo, including, but not limited to, the following: lowfat milk, skim milk, cream, half and half, dry milk, nonfat dry milk, dry cream, condensed or concentrated milk products, cultured or acidified milk or milk products, kefir, eggnog, yogurt, butter, cheese (where not specifically exempted by regulation), whey, condensed or dry whey or whey products, ice cream, ice milk, other frozen dairy desserts and products obtained by modifying the chemical or physical characteristics of milk, cream, or whey by using enzymes, solvents, heat, pressure, cooling, vacuum, genetic engineering, fractionation, or other similar processes, and any such product made by the addition or subtraction of milkfat or the addition of safe and suitable optional ingredients for the protein, vitamin, or mineral fortification of the product.

(k) *Minimum heat treatment*. The causing of all particles in garbage to be heated to a boiling temperature and held at that temperature for a period of not less than 30 minutes.

(l) *Possession*. Any of the possessions of the United States, including Puerto Rico and the Virgin Islands.

(m) *Potable water*. Water which meets the standards prescribed in the Environmental Protection Agency's Primary Drinking Water Regulations as set forth in 40 CFR part 141 and the Food and Drug Administration's sanitation requirements as set forth in this part and part 1250 of this chapter.

(n) *State*. Any State, the District of Columbia, Puerto Rico and the Virgin Islands.

(o) *Utensil*. Includes any kitchenware, tableware, glassware, cutlery, containers, or equipment with which food or drink comes in contact during storage, preparation, or serving.

(p) *Vessel*. Any passenger-carrying, cargo, or towing vessel exclusive of:

(1) Fishing boats including those used for shell-fishing;

(2) Tugs which operate only locally in specific harbors and adjacent waters;

(3) Barges without means of self-propulsion;

(4) Construction-equipment boats and dredges; and

(5) Sand and gravel dredging and handling boats.

(q) *Watering point*. The specific place or water boat from which potable water is loaded on a conveyance.

(r) *Molluscan shellfish*. Any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the product consists entirely of the shucked adductor muscle.

(s) *Certification number* means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

(t) *Shellfish control authority* means a Federal, State, or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

(u) *Tag* means a record of harvesting information attached to a container of shellstock by the harvester or processor.

[40 FR 5620, Feb. 6, 1975, as amended at 48 FR 11431, Mar. 18, 1983; 57 FR 57344, Dec. 4, 1992; 60 FR 65201, Dec. 18, 1995]

### § 1240.10 Effective bactericidal treatment.

Whenever, under the provisions of this part, bactericidal treatment is required, it shall be accomplished by one or more of the following methods:

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(a) By immersion of the utensil or equipment for at least 2 minutes in clean hot water at a temperature of at least 170 °F or for one-half minute in boiling water;

(b) By immersion of the utensil or equipment for at least 2 minutes in a lukewarm chlorine bath containing at least 50 ppm of available chlorine if hypochlorites are used or a concentration of equal bactericidal strength if chloramines are used;

(c) By exposure of the utensil or equipment in a steam cabinet at a temperature of at least 170 °F for at least 15 minutes or at a temperature of 200 °F for at least 5 minutes;

(d) By exposure of the utensil or equipment in an oven or hot air cabinet at a temperature of at least 180 °F for at least 20 minutes;

(e) In the case of utensils or equipment so designed or installed as to make immersion or exposure impractical, the equipment may be treated for the prescribed periods of time either at the temperatures or with chlorine solutions as specified above, (1) with live steam from a hose if the steam can be confined, (2) with boiling rinse water, or (3) by spraying or swabbing with chlorine solution;

(f) Any other method determined by the Commissioner of Food and Drugs, upon application of an owner or operator of a conveyance, to be effective to prevent the spread of communicable disease.

[40 FR 5620, Feb. 6, 1975, as amended at 54 FR 24900, June 12, 1989]

### Subpart B—Administrative Procedures

#### § 1240.20 Issuance and posting of certificates following inspections.

The Commissioner of Food and Drugs may issue certificates based upon inspections provided for in this part and part 1250. Such certificates shall be prominently posted on conveyances.

[40 FR 5620, Feb. 6, 1975, as amended at 48 FR 11431, Mar. 18, 1983]

#### § 1240.30 Measures in the event of inadequate local control.

Whenever the Commissioner of Food and Drugs determines that the meas-

ures taken by health authorities of any State or possession (including political subdivisions thereof) are insufficient to prevent the spread of any of the communicable diseases from such State or possession to any other State or possession, he may take such measures to prevent such spread of the diseases as he deems reasonably necessary, including inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of animals or articles believed to be sources of infection.

[40 FR 5620, Feb. 6, 1975, as amended at 48 FR 11431, Mar. 18, 1983]

#### § 1240.45 Report of disease.

The master of any vessel or person in charge of any conveyance engaged in interstate traffic, on which a case or suspected case of a communicable disease develops shall, as soon as practicable, notify the local health authority at the next port of call, station, or stop, and shall take such measures to prevent the spread of the disease as the local health authority directs.

### Subpart C [Reserved]

### Subpart D—Specific Administrative Decisions Regarding Interstate Shipments

#### § 1240.60 Molluscan shellfish.

(a) A person shall not offer for transportation, or transport, in interstate traffic any molluscan shellfish handled or stored in such an insanitary manner, or grown in an area so contaminated, as to render such molluscan shellfish likely to become agents in, and their transportation likely to contribute to the spread of communicable disease from one State or possession to another.

(b) All shellstock shall bear a tag that discloses the date and place they were harvested (by State and site), type and quantity of shellfish, and by whom they were harvested (i.e., the identification number assigned to the harvester by the shellfish control authority, where applicable or, if such identification numbers are not assigned, the name of the harvester or the name or registration number of the harvester's vessel). In place of the tag,

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bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the same information.

(c) All containers of shucked molluscan shellfish shall bear a label that identifies the name, address, and certification number of the packer or repacker of the molluscan shellfish.

(d) Any molluscan shellfish without such a tag, shipping document, or label, or with a tag, shipping document, or label that does not bear all the information required by paragraphs (b) and (c) of this section, shall be subject to seizure or refusal of entry, and destruction.

[40 FR 5620, Feb. 6, 1975, as amended at 60 FR 65202, Dec. 18, 1995]

### § 1240.61 Mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption.

(a) No person shall cause to be delivered into interstate commerce or shall sell, otherwise distribute, or hold for sale or other distribution after shipment in interstate commerce any milk or milk product in final package form for direct human consumption unless the product has been pasteurized or is made from dairy ingredients (milk or milk products) that have all been pasteurized, except where alternative procedures to pasteurization are provided for by regulation, such as in part 133 of this chapter for curing of certain cheese varieties.

(b) Except as provided in paragraphs (c) and (d) of this section, the terms “pasteurization,” “pasteurized,” and similar terms shall mean the process of heating every particle of milk and milk product in properly designed and operated equipment to one of the temperatures given in the following table and held continuously at or above that temperature for at least the corresponding specified time:

Temperature	Time
145 °F (63 °C) <sup>1</sup> .....	30 minutes.
161 °F (72 °C) <sup>1</sup> .....	15 seconds.
191 °F (89 °C) .....	1 second.

<sup>1</sup> If the fat content of the milk product is 10 percent or more, or if it contains added sweeteners, the specified temperature shall be increased by 5 °F (3 °C).

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Temperature	Time
194 °F (90 °C) .....	0.5 second.
201 °F (94 °C) .....	0.1 second.
204 °F (96 °C) .....	0.05 second.
212 °F (100 °C) .....	0.01 second.

(c) Eggnog shall be heated to at least the following temperature and time specification:

Temperature	Time
155 °F (69 °C) .....	30 minutes.
175 °F (80 °C) .....	25 seconds.
180 °F (83 °C) .....	15 seconds.

(d) Neither paragraph (b) nor (c) of this section shall be construed as barring any other pasteurization process that has been recognized by the Food and Drug Administration to be equally efficient in the destruction of microbial organisms of public health significance.

[52 FR 29514, Aug. 10, 1987, as amended at 57 FR 57344, Dec. 4, 1992]

### § 1240.62 Turtles intrastate and interstate requirements.

(a) *Definition.* As used in this section the term “turtles” includes all animals commonly known as turtles, tortoises, terrapins, and all other animals of the order Testudinata, class Reptilia, except marine species (families Dermachelidae and Chelonidae).

(b) *Sales; general prohibition.* Except as otherwise provided in this section, viable turtle eggs and live turtles with a carapace length of less than 4 inches shall not be sold, held for sale, or offered for any other type of commercial or public distribution.

(c) *Destruction of turtles or turtle eggs; criminal penalties.* (1) Any viable turtle eggs or live turtles with a carapace length of less than 4 inches which are held for sale or offered for any other type of commercial or public distribution shall be subject to destruction in a humane manner by or under the supervision of an officer or employee of the Food and Drug Administration in accordance with the following procedures:

(i) Any District Office of the Food and Drug Administration, upon detecting viable turtle eggs or live turtles with a carapace length of less than 4 inches which are held for sale or offered for any other type of commercial

or public distribution, shall serve upon the person in whose possession such turtles or turtle eggs are found a written demand that such turtles or turtle eggs be destroyed in a humane manner under the supervision of said District Office, within 10 working days from the date of promulgation of the demand. The demand shall recite with particularity the facts which justify the demand. After service of the demand, the person in possession of the turtles or turtle eggs shall not sell, distribute, or otherwise dispose of any of the turtles or turtle eggs except to destroy them under the supervision of the District Office, unless and until the Director of the Center for Veterinary Medicine withdraws the demand for destruction after an appeal pursuant to paragraph (c)(1)(ii) of this section.

(ii) The person on whom the demand for destruction is served may either comply with the demand or, within 10 working days from the date of its promulgation, appeal the demand for destruction to the Director of the Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. The demand for destruction may also be appealed within the same period of 10 working days by any other person having a pecuniary interest in such turtles or turtle eggs. In the event of such an appeal, the Center Director shall provide an opportunity for hearing by written notice to the appellant(s) specifying a time and place for the hearing, to be held within 14 days from the date of the notice but not within less than 7 days unless by agreement with the appellant(s).

(iii) Appearance by any appellant at the hearing may be by mail or in person, with or without counsel. The hearing shall be conducted by the Center Director or his designee, and a written summary of the proceedings shall be prepared by the person presiding. Any appellant shall have the right to hear and to question the evidence on which the demand for destruction is based, including the right to cross-examine witnesses, and he may present oral or written evidence in response to the demand.

(iv) If, based on the evidence presented at the hearing, the Center Di-

rector finds that the turtles or turtle eggs were held for sale or offered for any other type of commercial or public distribution in violation of this section, he shall affirm the demand that they be destroyed under the supervision of an officer or employee of the Food and Drug Administration; otherwise, the Center Director shall issue a written notice that the prior demand by the District Office is withdrawn. If the Center Director affirms the demand for destruction he shall order that the destruction be accomplished in a humane manner within 10 working days from the date of the promulgation of his decision. The Center Director's decision shall be accompanied by a statement of the reasons for the decision. The decision of the Center Director shall constitute final agency action, reviewable in the courts.

(v) If there is no appeal to the Director of the Center for Veterinary Medicine from the demand by the Food and Drug Administration District Office and the person in possession of the turtles or turtle eggs fails to destroy them within 10 working days, or if the demand is affirmed by the Director of the Center for Veterinary Medicine after an appeal and the person in possession of the turtles or turtle eggs fails to destroy them within 10 working days, the District Office shall designate an officer or employee to destroy the turtles or turtle eggs. It shall be unlawful to prevent or to attempt to prevent such destruction of turtles or turtle eggs by the officer or employee designated by the District Office. Such destruction will be stayed if so ordered by a court pursuant to an action for review in the courts as provided in paragraph (c)(1)(iv) of this section.

(2) Any person who violates any provision of this section, including but not limited to any person who sells, offers for sale, or offers for any other type of commercial or public distribution viable turtle eggs or live turtles with a carapace length of less than 4 inches, or who refuses to comply with a valid final demand for destruction of turtles or turtle eggs (either an unappealed demand by an FDA District Office or a demand which has been affirmed by the Director of the Center for Veterinary Medicine pursuant to appeal), or who

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fails to comply with the requirement in such a demand that the manner of destruction be humane, shall be subject to a fine of not more than \$1,000 or imprisonment for not more than 1 year, or both, for each violation, in accordance with section 368 of the Public Health Service Act (42 U.S.C. 271).

(d) *Exceptions.* The provisions of this section are not applicable to:

(1) The sale, holding for sale, and distribution of live turtles and viable turtle eggs for bona fide scientific, educational, or exhibitional purposes, other than use as pets.

(2) The sale, holding for sale, and distribution of live turtles and viable turtle eggs not in connection with a business.

(3) The sale, holding for sale, and distribution of live turtles and viable turtle eggs intended for export only, provided that the outside of the shipping package is conspicuously labeled "For Export Only."

(4) Marine turtles excluded from this regulation under the provisions of paragraph (a) of this section and eggs of such turtles.

(e) *Petitions.* The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to amend this regulation. Any such petition shall include an adequate factual basis to support the petition, and will be published for comment if it contains reasonable grounds for the proposed regulation. A petition requesting such a regulation, which would amend this regulation, shall be submitted to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

[40 FR 22545, May 23, 1975, as amended at 46 FR 8461, Jan. 27, 1981; 48 FR 11431, Mar. 18, 1983; 54 FR 24900, June 12, 1989; 59 FR 14366, Mar. 28, 1994; 66 FR 56035, Nov. 6, 2001; 70 FR 48073, Aug. 18, 2005]

## § 1240.65 Psittacine birds.

(a) The term psittacine birds shall include all birds commonly known as parrots, Amazons, Mexican double heads, African grays, cocatoos, macaws, parakeets, love birds, lorries, lorikeets, and all other birds of the psittacine family.

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(b) No person shall transport, or offer for transportation, in interstate traffic any psittacine bird unless the shipment is accompanied by a permit from the State health department of the State of destination where required by such department.

(c) Whenever the Surgeon General finds that psittacine birds or human beings in any area are infected with psittacosis and there is such danger of transmission of psittacosis from such area as to endanger the public health, he may declare it an area of infection. No person shall thereafter transport, or offer for transportation, in interstate traffic any psittacine bird from such area, except shipments authorized by the Surgeon General for purposes of medical research and accompanied by a permit issued by him, until the Surgeon General finds that there is no longer any danger of transmission of psittacosis from such area. As used in this paragraph, the term "area" includes, but is not limited to, specific premises or buildings.

## § 1240.75 Garbage.

(a) A person shall not transport, receive, or cause to be transported or received, garbage in interstate traffic and feed such garbage to swine unless, prior to the feeding, such garbage has received minimum heat treatment.

(b) A person transporting garbage in interstate traffic shall not make, or agree to make, delivery thereof to any person with knowledge of the intent or customary practice of such person to feed to swine garbage which has not been subjected to minimum heat treatment.

## Subpart E—Source and Use of Potable Water

### § 1240.80 General requirements for water for drinking and culinary purposes.

Only potable water shall be provided for drinking and culinary purposes by any operator of a conveyance engaged in interstate traffic, except as provided in §1250.84(b) of this chapter. Such water shall either have been obtained from watering points approved by the Commissioner of Food and Drugs, or, if treated aboard a conveyance, shall

have been subjected to treatment approved by the Commissioner of Food and Drugs.

[40 FR 5620, Feb. 6, 1975, as amended at 48 FR 11431, Mar. 18, 1983]

#### **§ 1240.83 Approval of watering points.**

(a) The Commissioner of Food and Drugs shall approve any watering point if (1) the water supply thereat meets the standards prescribed in the Environmental Protection Agency's Primary Drinking Water Regulations as set forth in 40 CFR part 141, and (2) the methods of and facilities for delivery of such water to the conveyance and the sanitary conditions surrounding such delivery prevent the introduction, transmission, or spread of communicable diseases.

(b) The Commissioner of Food and Drugs may base his approval or disapproval of a watering point upon investigations made by representatives of State departments of health or of the health authorities of contiguous foreign nations.

(c) If a watering point has not been approved, the Commissioner of Food and Drugs may permit its temporary use under such conditions as, in his judgment, are necessary to prevent the introduction, transmission, or spread of communicable diseases.

(d) Upon request of the Commissioner of Food and Drugs, operators of conveyances shall provide information as to watering points used by them.

[40 FR 5620, Feb. 6, 1975, as amended at 48 FR 11431, Mar. 18, 1983; 48 FR 13978, Apr. 1, 1983]

#### **§ 1240.86 Protection of pier water system.**

No vessel engaged in interstate traffic shall make a connection between its nonpotable water system and any pier potable water system unless provisions are made to prevent backflow from the vessel to the pier.

#### **§ 1240.90 Approval of treatment aboard conveyances.**

(a) The treatment of water aboard conveyances shall be approved by the Commissioner of Food and Drugs if the apparatus used is of such design and is so operated as to be capable of pro-

ducing and in fact does produce, potable water.

(b) The Commissioner of Food and Drugs may base his approval or disapproval of the treatment of water upon investigations made by representatives of State departments of health or of the health authorities of contiguous foreign nations.

(c) Overboard water treated on vessels shall be from areas relatively free of contamination and pollution.

[40 FR 5620, Feb. 6, 1975, as amended at 48 FR 11431, Mar. 18, 1983]

#### **§ 1240.95 Sanitation of water boats.**

No vessel engaged in interstate traffic shall obtain water for drinking and culinary purposes from any water boat unless the tanks, piping, and other appurtenances used by the water boat in the loading, transportation, and delivery of such drinking and culinary water, have been approved by the Commissioner of Food and Drugs.

[40 FR 5620, Feb. 6, 1975, as amended at 48 FR 11431, Mar. 18, 1983]

## **PART 1250—INTERSTATE CONVEYANCE SANITATION**

### **Subpart A—General Provisions**

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1250.3 Definitions.

### **Subpart B—Food Service Sanitation on Land and Air Conveyances, and Vessels**

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- 1250.22 General requirements.
- 1250.25 Source identification and inspection of food and drink.
- 1250.26 Special food requirements.
- 1250.27 Storage of perishables.
- 1250.28 Source and handling of ice.
- 1250.30 Construction, maintenance and use of places where food is prepared, served, or stored.
- 1250.32 Food-handling operations.
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- 1250.35 Health of persons handling food.
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### **Subpart C—Equipment and Operation of Land and Air Conveyances**

- 1250.40 Applicability.